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COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
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David T. Read  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

APR 9 2002

Dear Mr. Read:

A determination was made that U.S. Patent No. 5,808,665, which claims the medical device da VINCI™ System, is ineligible for patent term extension under 35 U.S.C. § 156 because the medical device da VINCI™ system underwent regulatory review under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA), not under section 515 of the FFDCA and, as a result, was not eligible for patent term extension. See Manual of Patent Examining Procedure, Section 2751, page 2700-14, Eighth edition (August 2001), citing In re Nitinol Medical Technologies Inc., 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also Baxter Diagnostics v. AVL Scientific Corp., 798 F. Supp. 612, 619-620; 25 USPQ2d 1428, 1434 (1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

In reply, on January 9, 2002, applicant explained that the regulatory review period of the product was as required by 35 U.S.C. 156(g)(3)(B), because regulatory review was conducted under Section 515 of the FFDCA, and the subsequent approval under the Act, albeit under section 510(k) of the Act, did not diminish the patent's eligibility for patent term extension. Applicant relies upon the Food and Drug Administration's prior conclusion that applicant met the statutory requirements for regulatory review in support of their argument that the patent is eligible for extension.

FDA is requested to comment upon the reply (a copy of which is enclosed) in order to assist the U.S. Patent and Trademark Office reconsider the final determination of ineligibility.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 872-9411  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to [Karin.Tyson@uspto.gov](mailto:Karin.Tyson@uspto.gov).

Karin Ferriter  
Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Sally Yeager  
Alcon Laboratories Inc.  
R&D Counsel Q-148  
6201 South Freeway  
Forth Worth TX 76134